

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: SAM F. LIPRIE)

SERIAL NUMBER: 09/681,302)

FILED: March 15, 2001)

FOR: FLEXIBLE SOURCE WIRE FOR
RADIATION TREATMENT OF
DISEASES)

) Group Art Unit:

) 3641

) Before the Examiner:

) Jack Keith

APPEAL BRIEF

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(1) REAL PARTY IN INTEREST

The real party in interest is Interventional Therapies, L.L.C.

(2) RELATED APPEALS AND INTERFERENCES

There are no interferences that may have a bearing on the present appeal. An appeal is currently pending, and an appeal brief has been filed in related United States Patent Application Serial No. 09/455,582, filed December 6, 1999 and in related United States Patent Application Serial No. 09/455,579, filed December 6, 1999.

(3) STATUS OF CLAIMS

Claims 1-32 are currently pending in the present application. A clean copy of claims 1-32, as amended, are attached hereto as Appendix 1. A Final Office Action was mailed on August 7, 2002, finally rejecting claims 1, 2, 4-18 and 20-32. Applicant appeals from the final rejection of claims 1, 2, 4-18 and 20-32.

(4) STATUS OF AMENDMENTS

Claims 1-32 were originally presented with the filing of the application on December 6, 1999. Claims 3 and 19 were withdrawn pursuant to an election of species dated September 18, 2001, Paper No. 5. Claims 5-7, 16 and 26 were amended in the Applicant's submission dated July 1, 2002, Paper No. 10.

(5) SUMMARY

The appealed claims are related to a unique source wire used to deliver a radioactive source to a remote treatment site. This source wire advantageously features a generally cylindrical, elongated housing tube, through which a flexible backbone wire, having a rounded end, extends to a point wherein the rounded end is adjacent a positioned, encapsulated radiation source or adjacent capsule into which a radiation source is provided. The housing tube is constructed of a material exhibiting little or no memory retention when bent. Thus, the housing tube possesses shape memory characteristics that permit the source wire to adequately and, more to the point, repeatedly navigate torturous regions of the body. (See *e.g.*, the Applicant's specification, page 3, lines 10-24; page 5, line 13- page 6, line 4).

Reference is made to the Applicant's Figures 1-3, which show features of construction of the presently presented source wire, which further provide resiliency and/or integrity to the wire such that repeated use may be made through torturous regions. The material of the outer, housing tube 12 already being discussed, a flexible backbone wire 14 is presented with rounded end 24 through a length of the housing tube 12 up to either of a radioactive source 36, which may be previously encapsulated by an encapsulating material 40, or to a thin walled capsule 20, into which a radioactive source 16 may be loaded. Such encapsulating material or thin-walled capsule both protects the radioactive source from damage and prevents contamination of the remainder of the wire, and contributes, in combination with the nickel and titanium alloy housing tube and flexible backbone wire to the resiliency and/or integrity of the wire, which permits such repeated use without risk of either partial or total failure of the wire. (See *e.g.*, the Applicant's specification at page 6, line 26 – page 7, line 3).

Thus, the aggregate result of the above features advantageously provides a resilient,

flexible wire useful in modern medicine for radiation treatment of diseases in remote areas of the body.

For the convenience of the Examiner and the Board, the three independent claims are reproduced below:

Independent claim 1 of the present application requires:

A flexible source wire for radiation treatment of diseases within a body, comprising:

a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;

a flexible backbone wire having a proximal end, said proximal end of said wire being disposed in said housing tube, and further wherein the proximal end of said backbone wire is rounded; and

a radiation source or sources provided within said housing tube, said proximal end of said flexible backbone wire being adjacent to said radiation source or sources.

Independent claim 14 of the present application requires:

A flexible source wire for radiation treatment of diseases within a body, comprising:

a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;

a flexible backbone wire having a proximal end, said proximal end of said wire inserted into said tube, and further wherein the proximal end of said backbone wire is rounded;

a radiation source or sources provided within said housing tube, said proximal end of said flexible backbone wire being adjacent to said radiation source or sources.

Independent claim 25 of the present application requires:

A flexible source wire for radiation treatment of diseases within a body, comprising:

a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;

a flexible backbone wire having a proximal end, said proximal end of said wire inserted into said tube, and further wherein the proximal end of said backbone wire is rounded;

a capsule inserted into the proximal of said flexible elongated housing tube;

a radiation source or sources inserted into said capsule; and

a plug which seals said proximal end of said housing tube.

(6) ISSUES

The following issues are drawn from the last (Final) Office Action on the merits (Paper No. 12):

- (A) Claims 1, 2, 4-18 and 20-32 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.
- (B) Claims 1, 2, 4-18 and 20-32 were rejected under 35 USC 103(a) as allegedly being obvious over U.S. Patent No. 5,282,781 to Liprie (hereinafter "Liprie") in combination with U.S. Patent No. 5,454,794 to Nariciso et al. (hereinafter "Nariciso") and U.S. Patent No. 5,230,348 to Ishibe et al. (hereinafter "Ishibe").
- (C) Claims 1, 2, 4-18 and 20-32 have been rejected under 35 USC 103(a) as allegedly being obvious over Liprie in combination with Nariciso, and further in combination with Ishibe, further in combination with U.S. Patent No. 5,163,896 to Suthanthiran et al. (hereinafter "Suthanthiran").

(7) GROUPING OF CLAIMS

The claims herein do not stand or fall together in so much as independent claim 25 recites inventive details not described by the other independent claims.

(8) ARGUMENT

(A) *The rejection of claims 1, 2, 4-18 and 20-32 under 35 U.S.C. §112, second paragraph.*

Claims 1, 2, 4-18 and 20-32 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Specifically, the Examiner has cited to the claim language within claims 1, 14 and 25 as being unclear whether the housing tube is positively recited as being part of the flexible source wire. The Applicant notes that each of claims 1, 14 and 25 explicitly recites "a flexible, hollow, elongated housing tube..." in the body of the claim. Because such is explicitly recited, it is a part of the flexible source wire.

The Examiner also noted concern with language describing "future acts" (specifically, the terminology "when bent"), indicating that such is not a positive structural limitation.

As a first point, whether the source wire is bent or straight is not a temporal limitation. The wire could be presently bent or presently straight (i.e., when claimed). There is no future action implied. Rather, such is a limitation that serves to define a characteristic of the materials of certain source wire components. In that respect, *In re Collier* does not apply.

As a second point, the decision in *In re Collier* is conditioned by the subsequent case *In The Matter Of The Application Of J. William Venezia*, 530 F.2d 956; 189 U.S.P.Q. (BNA) 149 (CCPA 1976). That case specifically discussed the *In re Collier* decision, noting that "conditional" language itself is not suspect, where such claims "precisely define present structural attributes of interrelated component parts...such that later assembly...may be effected." *Id* at 960.

For the above reasons, the rejection is improper and should be withdrawn.

(B) *The rejection of claims 1, 2, 4-18 and 20-32 under 35 USC 103(a) as allegedly being obvious over Liprie in combination with Nariciso, and further in combination with Ishibe.*

In order to make out a prima facie case of obviousness, a proposed combination of prior art references must teach or suggest all of the limitations of the rejected claims. *In re Vaech*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *E.g., ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). “The proposed modification cannot render the prior art unsatisfactory for its intended purpose.” MPEP 2143.01. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01, *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959).

As described above, the aggregate features of each of the independent claims at issue advantageously provide a resilient, flexible wire useful in modern medicine for radiation treatment of diseases in remote areas of the body. An outer, housing tube 12 comprises a material exhibiting little or no memory retention when bent, and at least partially contains a flexible backbone wire 14 having rounded end 24 presented through a length of the housing tube up to either of a radioactive source 36, which may be previously encapsulated by an

encapsulating material 40, or to a thin walled capsule 20, into which a radioactive source 16 may be loaded. Such encapsulating material or thin-walled capsule both protects the radioactive source from damage and prevents contamination of the remainder of the wire, and contributes, in combination with the nickel and titanium alloy housing tube and flexible backbone wire to the resiliency and/or integrity of the wire, which permits such repeated use without risk of either partial or total failure of the wire.

By contrast, the source wire taught and described by Liprie is an older generation of source wires, wherein a radioactive source is inserted directly into an open end of a housing tube (disclosed as one of stainless steel, titanium and tantalum (single metal composition, not alloyed)) and positioned between a backbone wire and a plug. The housing tube is then drawn down over the assembly to secure everything in place.

Review of the independent claims reproduced above reveals that the presently pending claims patentably distinguish over Liprie. As will be pointed out below, Liprie lacks particular required limitations described by the independent claims. Because all of the required claim limitations are not described by the cited references, an obviousness rejection is improper. In order to make out or sustain a rejection for obviousness, all of the claim limitations must be taught or suggested in the prior art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Each of independent claims 1, 14 and 25 may be readily distinguished over Liprie in that Liprie fails to teach or suggest a "housing tube contain a flexible backbone wire having a proximal end, said proximal end of said wire being disposed in said housing tube, and further wherein the proximal end of said backbone wire is rounded, and a radioactive source... said

proximal end of said flexible backbone wire being adjacent the radioactive source.” With respect to claim 25, Liprie additionally fails to teach or suggest a capsule containing a radioactive source and a flexible backbone wire having a rounded proximal end inserted in the housing tube such that the rounded proximal end of the backbone wire is adjacent the capsule.

Neither Narciso nor Ishibe describe a housing tube containing a radioactive source and a flexible backbone wire having a rounded proximal end adjacent the radioactive source. Similarly, Liprie does not teach a backbone wire having a rounded proximal end.

Liprie does not teach a backbone wire having a rounded proximal end. In the Office Action dated February 1, 2002, the Examiner claims that because the source wire is crimped, the backbone wire, which is illustrated as being flat in the Figures, would “bulb” under pressure, thus creating a rounded end.

Other than the fact that this is a supposition on the Examiner’s part rather than a teaching or description of the art, there are two problems with this reasoning. First, Liprie teaches that the backbone wire should be composed of an extremely high tensile strength material. *Col. 9, lines 35-39*. Such material would be resistant to “bulbing” as described by the Examiner.

Secondly, Liprie teaches that the backbone wire, radioactive core and plug should be closely abutting, such that they are tightly secured together by the force of the tube. *Col. 11, lines 14-18*. Indeed, the patent teaches that final drawdown of the tube onto the plug, core and backbone wire serves to eliminate virtually any remaining air spaces between confronting surfaces of components at the interior of the tube. *Col. 12, lines 10-20*.

Neither Narciso nor Ishibe describe a housing tube containing a radioactive source and a flexible backbone wire having a rounded proximal end adjacent the radioactive source. Narciso

merely describes a steerable catheter including a deflecting wire. Ishibe merely describes a guide wire with an internal wire running the length thereof.

In the Office Action of February 1, 2002, the Examiner claims that Ishibe describes a bulb wire end at the distal end of the guide wire, the bulb effective to prevent piercing of the material of the distal end of the guide wire. The Examiner claims that such teaching is relevant to Liprie, and thus properly combinable with Liprie, since such a backbone wire would not promote flaking of the radioactive core. However, Liprie actually teaches away from Ishibe's design. As noted above, Liprie requires a tight fit of internal components (a bulb end would not promote such a tight fit; flaking of the radioactive source in the manufactured wire is not a concern for the wire of Liprie) as well as a minimization of all internal air space within the housing tube (In addition to the reasons stated above, Liprie states "A key aspect of the source wire fabricated according to the method of the present invention is that radioactivity emanating from the core will not seriously affect the interior surfaces or structure of the source wire, because the lack of air in the assembled unit will not allow undesirable reactions such as oxidation to take place." *Col. 12, lines 14-20*).

The Examiner's rejection of the claims is improper for any and all of the reasons above. Accordingly, all of the Examiner's rejections should be withdrawn.

Additionally, with regard to independent claim 25, none of Narciso, Ishibe and Liprie describe a capsule containing a radioactive source and a flexible backbone wire having a rounded proximal end inserted in the housing tube such that the rounded proximal end of the backbone wire is adjacent the capsule. The Examiner has not identified any prior art teaching such capsule, provided adjacent the rounded proximal end of the backbone wire. Accordingly, the Examiner

has not made out a prima facie case of obviousness.

Because the prior art references do not disclose the above required claim limitation, the proposed combination is improper in that it does not present a prima facie case of obviousness. The Examiner's rejection should be withdrawn.

(C) The rejection of claims 1, 2, 4-18 and 20-32 under 35 USC 103(a) as allegedly being obvious over Liprie in combination with Nariciso, and further in combination with Ishibe, further in view of Suthanthiran

The presently pending claims are patentable over Liprie in view of Narciso, Ishibe and Suthanthiran for substantially the same reasons as the above discussion with reference to the rejection over Liprie in view of Nariciso and Ishibe. Suthanthiran does not address the deficiencies of the above cited art. Indeed, Suthanthiran simply addresses production of radioactive seeds, coated with, e.g., titanium materials, for direct placement in the body. Accordingly, the entirety of the discussion at (B) above is incorporated by reference.

Additionally, Suthanthiran does not describe a capsule, provided within a flexible, elongated housing tube, such as is required by claim 25. For this reason alone, the Examiner's rejection should be withdrawn with reference to claim 25.

Finally, the requisite motivation to combine Suthanthiran and Liprie is lacking.

As discussed above, Liprie calls (1) for a radioactive source to be directly inserted within a housing tube between a backbone wire and a plug and (2) for the tube to be drawn down to secure each element in place. Liprie teaches that the drawing down process removes all air space. This removal of air space prevents migration of radioactive flakes.

When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *E.g., ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). “The proposed modification cannot render the prior art unsatisfactory for its intended purpose.” MPEP 2143.01. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01, *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959).

The proper motivation to combine Suthanthiran and Liprie is not present. Suthanthiran does not suggest the desirability of including the seed within any other devices, and Liprie does not suggest the desirability of including within the wire what would ordinarily be designed for direct intracorporeal use. The references do not suggest the desirability of such combination, and the Examiner cannot draw such motivation from the Applicant’s roadmap. As stated in W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983),

[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. ... One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

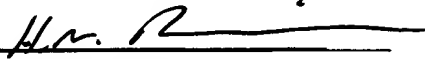
Because the requisite motivation to combine is lacking, the Examiner’s rejections should be withdrawn.

(9) CONCLUSION

The rejections of the claims are in error and should be reversed.

Respectfully submitted,
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APPENDIX I

1. A flexible source wire for radiation treatment of diseases within a body comprising:
a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;
a flexible backbone wire having a proximal end, said proximal end of said wire being disposed in said housing tube, and further wherein the proximal end of said backbone wire is rounded; and
a radiation source or sources provided within said housing tube, said proximal end of said flexible backbone wire being adjacent to said radiation source or sources.
2. The flexible source wire in accordance with claim 1 further including a plug which is sealed to said proximal end of said housing tube.
3. The flexible source wire of claim 1, wherein said radioactive source is encapsulated within a neutron permeable material.
4. The flexible source wire of claim 1, wherein said radioactive source is included within a thin walled-capsule.
5. The flexible source wire in accordance with claim 1 wherein said housing tube is constructed from a titanium/nickel alloy.
6. The flexible source wire in accordance with claim 2 wherein said housing tube is constructed from a titanium/nickel alloy.

7. The flexible source wire in accordance with claim 3 wherein said housing tube is constructed from a titanium/nickel alloy.
8. The flexible source wire in accordance with claim 1 wherein a portion of the inner surface of said proximal end of said housing tube exhibits a tapered funnel shape for ease of loading said radioactive source or sources within said flexible housing tube.
9. The flexible source wire in accordance with claim 1, wherein said backbone wire is completely disposed in said housing tube.
10. The flexible source wire in accordance with claim 1 wherein said backbone wire is affixed to the interior wall of said flexible housing tube at one or more locations.
11. The flexible source wire in accordance with claim 1, wherein said backbone wire includes a distal end, and wherein said distal end is disposed within said tube.
12. The flexible source wire in accordance with claim 1 wherein the outer surface of said housing tube is coated with a non-oxidizing agent.
13. The flexible source wire in accordance with claim 12 wherein said non-oxidizing agent is gold.
14. A flexible source wire for radiation treatment of diseases within a body comprising:
 - a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;
 - a flexible backbone wire having a proximal end, said proximal end of said wire inserted into said tube, and further wherein the proximal end of said backbone wire is rounded;

a radiation source or sources provided within said housing tube, said proximal end of said flexible backbone wire being adjacent to said radiation source or sources.

15. The flexible source wire in accordance with claim 14 further including a plug, which is sealed to said proximal end of said housing tube.

16. The flexible source wire in accordance with claim 14 wherein said housing tube is constructed from a titanium/nickel alloy.

17. The flexible source wire in accordance with claim 14 wherein a portion of the inner surface of said proximal end of said housing tube exhibits a tapered funnel shape for ease of loading said radioactive source or sources within said flexible housing tube.

18. The flexible source wire of claim 14, wherein the radioactive source is included within a thin-walled capsule.

19. The flexible source wire of claim 14, wherein the radioactive source is encapsulated within a neutron permeable material.

20. The flexible source wire in accordance with claim 14, wherein said backbone wire is completely inserted in said housing tube.

21. The flexible source wire of claim 14, wherein the backbone wire includes a distal end, and wherein the backbone wire is completely inserted such that the distal end is disposed within the tube.

22. The flexible source wire in accordance with claim 14, wherein said backbone wire is affixed to the interior wall of said flexible housing tube at one or more locations.

23. The flexible source wire in accordance with claim 14 wherein the outer surface of said housing tube is coated with a non-oxidizing agent.
24. The flexible source wire in accordance with claim 14 wherein said non-oxidizing agent is gold.
25. A flexible source wire for radiation treatment of diseases within a body comprising:
a flexible, hollow, elongated housing tube having a distal end and a proximal end, said housing tube constructed from a material exhibiting little or no memory retention when bent;
a flexible backbone wire having a proximal end, said proximal end of said wire inserted into said tube, and further wherein the proximal end of said backbone wire is rounded;
a capsule inserted into said proximal end of said flexible elongated housing tube;
a radiation source or sources inserted into said capsule; and
a plug which seals said proximal end of said housing tube.
26. The flexible source wire in accordance with claim 25 wherein said housing tube is constructed from a titanium/nickel alloy.
27. The flexible source wire in accordance with claim 25 wherein a portion of the inner surface of said proximal end of said housing tube exhibits a tapered funnel shape for ease of loading said radioactive source or sources within said flexible housing tube.
28. The flexible source wire in accordance with claim 25, wherein said backbone wire is completely disposed in said housing tube

29. The flexible source wire of claim 25, wherein the backbone wire includes a distal end, and wherein the backbone wire is completely inserted such that the distal end is disposed within the tube.

30. The flexible source wire in accordance with claim 25 wherein said backbone wire is affixed to the interior wall of said flexible housing tube at one or more locations.

31. The flexible source wire in accordance with claim 25 wherein the outer surface of said housing tube is coated with a non-oxidizing agent.

32. The flexible source wire in accordance with claim 31 wherein said non-oxidizing agent is gold.